IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

05 - 11438 JLT

ELIZABETH WALSH
28 Glenrose Road
Dorchester, MA 02124

MAGISTRATE JUDGE

Plaintiff,

vs.

Civil Action No: _____

WYETH, INC.
5 Giralda Farms
Madison, New Jersey 07940

SERVE: Lane Heard
725 Twelfth Street, NW
Washington, DC 20005

and

WYETH PHARMACEUTICALS INC.
500 Arcola Drive
Collegeville, Pennsylvania 19426

SERVE: Lane Heard
725 Twelfth Street, NW
Washignton, DC 20005

PFIZER, INC.
235 East 42nd Street
New York, New York, 10017

SERVE: Alys M. Kremer
150 E. 42nd Street
New York, NY 10017

RECEIPT # 65475
AMOUNT $ 250
SUMMONS ISSUED 4
LOCAL RULE 4.1
WAIVER FORM
MCF ISSUED
BY DPTY. CLK.
DATE 7/8/05

GREENSTONE, LTD.
7000 Portage Road
Kalamazoo MI 49001

SERVE: Alys M. Kremer
150 E. 42nd Street
New York, NY 10017

And

PHARMACIA & UPJOHN COMPANY
100 Route 206 North
Peapack, New Jersey, 07977

SERVE: Alys M. Kremer
150 E. 42nd Street
New York, NY 10017

Defendants.

PLAINTIFFS' COMPLAINT AND JURY DEMAND

NOW COMES the Plaintiff, Elizabeth Walsh, by and through her attorneys, Pollack & Flanders, LLP., and for their causes of action, sue the Defendants, and allege as follows:

PREAMBLE

Since the first estrogen pill was introduced in 1942, makers of synthetic sex hormones have created a marketing and cultural phenomenon. Drug companies' claims to support the use of hormone therapy were never backed by reliable scientific evidence, despite a flood of drug-company promotions.

In July, 2002, federal officials abruptly stopped a trial of hormone therapy drugs that was being conducted by the Women's Health Initiative (WHI). The WHI trial revealed that women taking Prempro, a combination of estrogen and progestin hormones, experienced an increased incidence of breast cancer, heart disease and stroke. Another study published later the same month showed that women taking estrogen-only pills were at greater risk to develop ovarian cancer. The *New England Journal of Medicine* concluded in February, 2003, that the "risks of breast cancer, venous thromboembolism, and stroke are too high a price to pay" for unsubstantiated benefits of hormone therapy.

Subsequent studies following WHI demonstrate conclusively that evidence-based medicine took a back seat to "conventional wisdom." The *New England Journal of Medicine* wrote in October, 2003:

> The simple and intuitively appealing concept that replacing estrogen lost during menopause would be beneficial was easy for both patients and physicians to believe. . . . *As a result, many people suspended ordinary standards of evidence* concerning medical interventions . . . despite the absence of any large scale clinical trial quantifying its overall risk-benefit ratio. [Emphasis added].

The Plaintiffs in this lawsuit will prove that these hormone drugs were unreasonably dangerous for any long term use, and that the Defendants promoted synthetic hormone drug therapy without conducting appropriate long-term, clinical trials to support their claims. The Plaintiffs will further prove that Wyeth pushed hormone therapy onto the medical community, without sufficient warnings. Had

Wyeth acted appropriately, thousands of women nationwide, and the Plaintiffs herein, would not have been injured by these drugs.

I. PARTIES

1. Plaintiff Elizabeth Walsh is a United States citizen, residing at 28 Glenrose Road, Dorchester, Massachusetts.
2. Defendant **Wyeth, Inc.** is a Delaware corporation with a principal place of business located at 5 Giralda Farms, Madison, New Jersey. At all times relevant hereto, Wyeth was engaged in , *inter alia*, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling of hormone therapy drugs, including Premarin, Prempro, and medroxyprogesterone acetate. Plaintiff alleges on information and belief that Wyeth, Inc., does business in the Commonwealth of Massachusetts and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drugs Premarin, Prempro and medroxyprogesterone acetate.
3. Defendant **Wyeth Pharmaceuticals Inc.** is a Delaware corporation with headquarters and a principal place of business located at 500 Arcola Drive, Collegeville, Pennsylvania. At all times relevant hereto, Wyeth Pharmaceuticals Inc., was engaged in, *inter alia*, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling of hormone therapy drugs, including Premarin, Prempro, and medroxyprogesterone acetate. Plaintiff alleges on information and belief that Wyeth Pharmaceuticals, Inc., does business in the Commonwealth of Massachusetts and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drugs Premarin, Prempro and medroxyprogesterone acetate.

4. Defendant **GREENSTONE, LTD**, is a Delaware corporation headquartered and with a principal place of in New Jersey and is a wholly owned subsidiary of Pharmacia & Upjohn Company, LLC. Upon information and belief Greenstone was engaged in, *inter alia*, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including medroxyprogesterone acetate. Plaintiff alleges on information and belief that Greenstone, LTD, does business in Massachusetts and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drug medroxyprogesterone acetate.

5. Defendant **PHARMACIA & UPJOHN COMPANY, LLC** is a Delaware corporation headquartered and with a principal place of business at 100 Route 206 North, Peapack, New Jersey. At all times relevant hereto, Pharmacia & Upjohn Company, LLC was engaged in, *inter alia*, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including medroxyprogesterone acetate. Pharmacia & Upjohn Co., LLC is wholly owned by Pfizer Incorporated. Plaintiff alleges on information and belief that Pharmacia & Upjohn Company, does business in Massachusetts and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drug medroxyprogesterone acetate.

6. Defendant **PFIZER INCOROPERATED** is a Delaware corporation headquartered and with a principal place of business at 235 East 42nd Street, New York, New York. At all times relevant hereto, Pfizer, Inc. was engaged in, *inter alia*, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including

medroxyprogesterone acetate. Plaintiff alleges on information and belief that Pfizer, Inc. does business in Massachusetts and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drug medroxyprogesterone acetate.

II. JURISDICTION/ VENUE

7. The amount in controversy exceeds seventy-five thousand dollars ($75,000.00) exclusive of costs and interest, and diversity jurisdiction exists pursuant to 28 U.S.C. §1332.

8. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391.

9. The Defendants committed a tortious act within the Commonwealth of Massachusetts causing injury to Plaintiffs. Defendants regularly do or solicit business or engage in other persistent courses of conduct or derive substantial revenues from goods used and consumed in the Commonwealth of Massachusetts, or for services rendered in the Commonwealth of Massachusetts, and said Defendants expected or reasonably should have expected that their tortious acts would have consequences in the Commonwealth of Massachusetts, and Defendants derive substantial revenue from interstate and/or international commerce, including the Commonwealth of Massachusetts.

10. The Defendants committed a tortious act within the Commonwealth of Massachusetts by marketing, distributing, retailing and selling a dangerous and defective drug within the Commonwealth of Massachusetts to Plaintiff Elizabeth Walsh and/or anyone else who may have consumed the defective product, and did cause serious and permanent injury to the Plaintiff.

11. The Defendants regularly solicited business within the Commonwealth of Massachusetts and engaged in the persistent course of conduct of distributing, retailing and transporting certain of its products within the Commonwealth of Massachusetts and to many of the other states within the United States, and derived substantial revenues from goods or services rendered in the Commonwealth of Massachusetts.

III. FACTUAL BACKGROUND

A. Case Specific Facts

12. Elizabeth Walsh was under the routine care of Donna Richardson M.D. of Boston, Massachusetts.

13. In approximately 1990, Dr. Richardson prescribed Premarin for Mrs. Walsh in response to her symptoms of menopause.

14. Subsequent to the initial diagnosis, Dr. Richardson changed Mrs. Walsh's hormone therapy medication to Prempro. Mrs. Walsh continued to take Prempro, as prescribed, through August, 2002.

15. On or about July 15, 2002, Mrs. Walsh presented with exertional pain in her right calf.

16. After undergoing an arteriogram, Mrs. Walsh underwent femoral artery by-pass.

17. As a direct result of being prescribed and taking Premarin, and then Prempro, Plaintiff Elizabeth Walsh was diagnosed with blockage in her femoral artery, suffered severe conscious pain and suffering, mental anguish, damage to the marital relationship, lost economic benefits as well as expenses for care, treatment and hospitalization among other damages.

B. The Marketing of Hormone Therapy

18. Menopause is the cessation of menstruation caused by declining levels of estrogen and progesterone. It is a natural human phenomenon -- a phase of the female reproductive aging process -- not a disease. Symptoms, which vary in severity from woman to woman, may include hot flashes, chills, vaginal dryness, headache and irritability. Adverse consequences of the drop in estrogen levels which begin with menopause and continue after menopause include, *inter alia*, vaginal atrophy and dryness; an increase in LDL cholesterol levels; and, a decrease in bone density with resultant increased risk of osteoporosis.

19. These symptoms and consequences of menopause have been described in scientific literature since the late 1800s, and by the turn of the 20th century, the search for an aid to alleviate them was widely pursued.

20. In 1942, Ayerst, the predecessor to Wyeth, received patent and FDA approval for Premarin, a mix of estrogens extracted from the urine of pregnant mares. Premarin was marketed to women and their physicians as the long sought after replacement for lost estrogen in menopausal women, and was referred to as "replacement" estrogen therapy.

21. The FDA originally approved Premarin only to relieve menopausal symptoms, such as hot flashes and vaginal atrophy. Wyeth, however, has long touted additional benefits for Premarin, and its subsequently marketed hormone therapy drugs, Prempro and medroxyprogesterone acetate.

22. In the 1960s, Wyeth's Premarin promotional materials used articles and books written by Dr. Robert Wilson. Dr. Wilson, a Brooklyn, New York, gynecologist, recommended that women use Premarin for reasons far beyond those approved by the FDA. In a 1962 article which

appeared in the *Journal of the American Medical Association* (*JAMA*), Dr. Wilson claimed that taking estrogen during menopause *reduced* breast and genital cancers. In his 1966 book, Feminine Forever– which Wyeth's sales forces distributed to physicians throughout the country – Dr. Wilson wrote that "aside from keeping a woman sexually attractive and potent . . . estrogen preserves the strength of her bones, the glow of her skin, the gloss of her hair. . . . Estrogen makes women adaptable, even-tempered, and generally easy to live with." In the book, Dr. Wilson again asserted that estrogen prevented cancers.

23. Following Dr. Wilson's publications, sales of Premarin quadrupled. Wyeth poured thousands of dollars into Dr. Wilson's research. By the mid-1970s, more than 30 million prescriptions for Premarin were being written every year, eventually making it the fifth most frequently prescribed drug in the United States.

24. Physicians were instructed in advertisements to prescribe Premarin to achieve "tranquilizing" effects for their female patients – as if that effect was a laudable goal: "Almost any tranquilizer might calm her down . . . but at her age, estrogen may be what she really needs."

25. The promotional advertising downplayed the risks of hormone therapy and over promoted the benefits. A 1970s article in *Harper's Bazaar* claimed: "There doesn't seem to be a sexy thing estrogen can't and won't do to keep you flirtatiously feminine for the rest of your days . . . a real package deal that spruces up your vagina. . . . Prevalent medical opinion is that the safety and benefits of ERT have been convincingly demonstrated."[1]

[1] "ERT" is shorthand for Estrogen Replacement Therapy (e.g., Premarin taken alone).

26. But the "safety and benefits" of Premarin were cast in serious doubt following a 1976 study published in the *New England Journal of Medicine* evidencing a causal relationship between estrogen and endometrial cancer. Sales plummeted, and physicians stopped prescribing Premarin except to those women who had hysterectomies and thus were not at risk for endometrial cancer.

27. A 1980 medical article suggested a solution. Dr. Don Gambrell, a reproductive endocrinologist, reported in the journal *Obstetrics and Gynecology* that adding progestin to estrogen led to a *decline* in endometrial cancer. Wyeth thus produced and marketed progestin (i.e., synthetic progesterone or medroxyprogesterone acetate) as an adjunct to Premarin estrogen hormone therapy to protect against the risk of endometrial cancer.

28. Wyeth manufactures, sells and distributes medroxyprogesterone acetate for use in combination with Premarin under trademarked brand names such as Provera and Cycrin, and as generic equivalents. And, Prempro has the added synthetic progesterone.

29. Additional claims were made in the 1980s when Wyeth promoted hormone therapy to help prevent bone loss, and when Wyeth claimed that hormone therapy drugs could prevent cardiovascular disease. By claiming that hormone therapy drugs prevented osteoporosis and cardiovascular disease, Wyeth was able to promote Premarin as recommended treatment for all women, regardless of whether they were experiencing menopause. As a result, between 1990 and 1995, Premarin became the most frequently dispensed prescription drug in the United States.

30. Premarin's huge success was bolstered by claims that indefinite, long term use of estrogen therapy was safe and efficacious. In an early 1990s promotional videotape distributed directly to

consumers entitled *"What Every Woman Should Know About Estrogen,"* Wyeth represented to women that estrogen provided "long term health protection" and should be continued indefinitely, even after short-term menopausal symptoms, such as hot flashes, had subsided. When a purported consumer inquired how long Premarin should be taken, Wyeth's doctor-spokesperson responded, "Anywhere from five to ten years in order to get protection from long term problems." And, with regard to breast cancer risks, Wyeth represented to women that the benefits of taking estrogen "far outweigh[ed]" the risks for women unless they faced a particularly high risk of breast cancer.

31. Prior to 1995, Wyeth began to develop a combination therapy pill that would combine Premarin with progestin. This product development was necessary because Wyeth faced the threat of a shrinking market for Premarin at the end of its patent protection in 1995.

32. In 1995 Wyeth introduced Prempro, "combination" hormone therapy that contained estrogen and medroxyprogesterone acetate (synthetic progestins).

33. Wyeth led physicians and consumers to believe the promotional claims it made regarding Premarin. Likewise, when Wyeth introduced Prempro to the market, physicians and consumers were again led to believe that these attributes existed for this hormone therapy, as Wyeth had claimed about Premarin.

34. Wyeth over-promoted Prempro, just as it did Premarin. For example, Wyeth distributed a brochure that asked women to "Take a few minutes to think about the rest of your life," and then listed medical conditions to "think about" which neither Prempro nor Premarin had been

approved by the FDA to treat, including Alzheimer's disease, vision problems, tooth loss, heart disease, and colon cancer.

35. In a magazine advertisement featuring model Lauren Hutton, Wyeth made a rash of similar claims, suggesting that its hormone therapy drugs were appropriate for treating or preventing, among other things, memory loss, colon cancer, and age-related vision loss. In the March 19, 2000, edition of *Parade Magazine,* Wyeth spokesperson Lauren Hutton (who was not identified as a Wyeth spokesperson) was asked what she did to look good and feel fit, and she answered: "[M]y number one secret is estrogen. It's good for your moods; it's good for your skin. If I had to choose between all my creams and makeup for feeling and looking good, I'd take the estrogen.

36. Wyeth's DTC (i.e., "direct-to-consumer" or "DTC" marketing) efforts have included overt advertising pieces, such as print advertisements, videotapes, and brochures directed to consumers, as well as "product placement" efforts in which hormone therapy drugs are favorably positioned in entertainment vehicles or favorably described in the popular press by hired spokespersons.

37. Wyeth vigorously promoted hormone therapy to physicians, as well as to consumers directly. In 1999, Wyeth spent $34.7 million on DTC advertising for Prempro. In 2000, Wyeth spent $37.4 million on Prempro DTC advertising. The thrust of Wyeth's marketing efforts has been to create a lifelong consumer demand for hormone therapy, and a belief by physicians that the prescription is beneficial to menopausal and post-menopausal patients.

C. <u>The WHI and NCI Studies</u>

38. Wyeth's promotion of hormone therapy for long-term use proved false and misleading when studies released in July, 2002 showed that such use substantially increases the risk of *causing* disease.

39. Two large cohort studies concluded that the risks of hormone therapy outweighed the benefits for most women: The WHI study, reported at Roussow JE, et al., *Risks and Benefits of Estrogen Plus Progestin in Healthy Post-menopausal Women.* (JAMA. 2002 Jul 17; 288:321-33.); and, the NCI study, reported at Lacey JV Jr., et al., *Menopausal Hormone Replacement Therapy and Risk of Ovarian Cancer.* (JAMA. 2002 Jul 17; 288(3):334-41.)

40. The Women's Health Initiative (WHI) is a group focused on defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in post-menopausal women. Between 1993 and 1998, the WHI enrolled 161,809 post-menopausal women in the age range of 50 to 79 years into a set of clinical trials and an observational study at 40 clinical centers in the United States. Included within the clinical trials was a study by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

41. Participants in the NHLBI component of WHI, like most women with a uterus who take hormone therapy, were given progestin in combination with estrogen (i.e., combination hormone therapy). The estrogen plus progestin trial of the WHI involved 16,608 women ages 50 to 79 years with an intact uterus. An important objective of the trial was to examine the effect of estrogen plus progestin on the prevention of heart disease and hip fractures, and any associated

change in risk for breast and colon cancer. The study did not immediately address the short-term risks and benefits of hormones for the treatment of menopausal symptoms.

42. Women enrolled in the estrogen plus progestin study were randomly assigned to a daily dose of estrogen plus progestin (0.625 mg of conjugated equine estrogens plus 2.5 mg of medroxyprogesterone acetate) or to a placebo. Those participants receiving the drug (not placebo) received Wyeth's drug Prempro. Participants were enrolled in the study between 1993 and 1998 at over 40 clinical sites across the country.

43. In 2000 and again in 2001, WHI investigators complied with a recommendation from the study's Data and Safety Monitoring Board (DSMB) to inform participants of a small increase in heart attacks, strokes, and blood clots in women taking hormones. The DSMB, an independent advisory committee charged with reviewing results and ensuring participant safety, found that the actual number of women having any one of these events was small and did not cross the statistical boundary established to ensure participant safety. Therefore, the group recommended continuing the trial due to the still uncertain balance of risks and benefits.

44. At the DSMB's meeting on May 31, 2002, the data review revealed for the first time that the number of cases of invasive breast cancer in the estrogen plus progestin group had crossed the boundary established as a signal of increased risk. The DSMB's May 31, 2002 recommendation to stop the trial was based on the finding of increased breast cancer risk, supported by the evidence of overall health risks exceeding any benefits. On July 8, 2002, participants started receiving letters informing them about the results and telling them that they should stop study medications.

45. The WHI Study found that for the estrogen plus progestin group (i.e., those women who took Prempro) compared to placebo, overall there was a:

(I) 41 percent increase in strokes,

(ii) 29 percent increase in heart attacks,

(iii) 100 percent increase in venous thromboembolism (blood clots),

(iv) 22 percent increase in total cardiovascular disease,

(v) 26 percent increase in breast cancer,

(vi) 37 percent reduction in cases of colorectal cancer, and

(vii) one-third reduction in hip fracture rates.

46. The WHI Study concluded that the "Overall health risks exceeded benefits from use of combined estrogen plus progestin for an average 5.2-year follow-up among healthy post-menopausal US women." The Study also found that the combination hormone regimen should not be initiated or continued for primary prevention of coronary heart disease.

47. Because of the importance of the report from the WHI investigators on the estrogen plus progestin study, the study was released early to the public on July 9, 2002, as an expedited article on the *JAMA* Website. In commenting on the studies findings, NHLBI Director, Dr. Claude Lenfant, was unequivocal in his own conclusions:

> The cardiovascular and cancer risks of estrogen plus progestin outweigh any benefits—and a 26 percent increase in breast cancer risk is too high a price to pay, even if there were a heart benefit. Similarly, the risks outweigh the benefits of fewer hip fractures.

48. Dr. Jacques Roussow, acting director of the WHI and lead author of the JAMA article, summarized the risks of combination hormone therapy in a very straightforward manner as he explained the statistical significance of the study results:

> The WHI results tell us that during one year, among 10,000 post-menopausal women with a uterus who are taking estrogen plus progestin, ***eight more will have invasive breast cancer, seven more will have a heart attack, eight more will have a stroke, and 18 more will have blood clots, including eight with blood clots in the lungs***, than will a similar group of 10,000 women not taking these hormones. This is a relatively small annual increase in risk for an individual woman. Individual women who have participated in the trial and women in the population who have been on estrogen and progestin

> should not be unduly alarmed. However, even small individual risks over time, and on a population-wide basis, add up to ***tens of thousands of these serious adverse health events***.

(Emphasis added.)

49. Within a week after the WHI results were reported, another article appeared in JAMA related to the risk of long-term use of estrogen-only therapy. On July 17, 2002, JAMA published a NCI study, which found that women who took estrogen were more likely to develop ovarian cancer than those not on the hormone.

50. In the study, researchers from the NCI followed 44,241 women for 19 years who were taking only estrogen and found that these women had a 60 percent higher risk of ovarian cancer than women who had never used estrogen. The risk increased proportionately with longer duration of estrogen use. Women who took estrogen for 10 to 19 years had an 80 percent higher risk than those who did not take the pills. Those on the hormone therapy for 20 years or more were three times as likely to develop ovarian cancer as women who did not take it at all. Most of the NCI participants used Wyeth's brand of estrogen therapy, Premarin.

51. Lead author of the NCI study, Dr. James V. Lacey, summarized the results of his study with the following statement:

> The main finding of our study was that post-menopausal women who used estrogen replacement therapy for 10 or more years were at significantly higher

> risk of developing ovarian cancer than women who never used hormone replacement therapy.

52. Dr. Lacey further underscored the implications of his NCI study by explaining that the findings translate into one or two additional ovarian cancers each year per 10,000 women taking estrogen alone. In 2000, eight million American women took Premarin, the leading estrogen therapy pill. The Lacey study demonstrates that Premarin usage is responsible for up to 1,600 additional ovarian cancer cases in the year 2000 alone.

53. In October 2003, the WHI study produced a report with findings similar to the NCI study regarding ovarian cancer. The October 1, 2003, issue of JAMA reported that combination hormone therapy was also associated with increased risk for ovarian cancer: the WHI investigators found that women randomized to received combined hormone therapy (i.e., estrogen plus progestin) experienced a 58 percent increase in ovarian cancer rates.

D. <u>The Aftermath of the WHI and NCI Studies</u>

54. The WHI and NCI studies received enormous media coverage: front-page newspaper headlines, magazine covers, and broadcast news programs urgently reported the alarming and significant findings.

55. Commenting on the WHI study, Dr. Leslie Ford, associate director for clinical research at the NCI's Division of Cancer Prevention, re-emphasized the risk of hormone therapy to patients:

> The reduction in colorectal cancer risk in the WHI is intriguing, but the balance of harm versus benefit does not justify any woman beginning or continuing to take estrogen plus progestin for this purpose.

56. Dr. Isaac Schiff of Massachusetts General Hospital also commented on the WHI study, noting, "Quality of life is very, very important . . . . From a heart and breast cancer point of view, the drug should be outlawed. But for hot flashes, there's nothing better."

57. The WHI and NCI study conclusions regarding the unsafe and dangerous adverse effects of hormone therapy have been verified by subsequent published research. A study on hormone therapy and breast carcinoma risk in Hispanic and non-Hispanic women, reported on September 1, 2002, in the journal *Cancer*, found that Hispanic post-menopausal women have significantly increased breast cancer risk after long-term hormone therapy.

58. On October 23, 2002, the United Kingdom's Medical Research Council announced that it had ended a clinical study of the risks and benefits of long-term use of hormone therapy for "scientific and practical reasons." Approximately 5,700 women were enrolled in the "WISDOM" study (the Women's International Study of Long Duration Oestrogen after Menopause). The study was to include 22,000 women. However, following the WHI study, the WISDOM study was canceled. The Medical Research Council concluded "There is strong evidence that taking hormone therapy long term increases the risks of some diseases such as breast cancer and decreases the risks of others such as osteoporosis."

59. Because of the significance of its findings, on March 17, 2003, the New England Journal of Medicine (NEJM) released a follow-up WHI study two months in advance of its May 8, 2003 publication date. The follow-up study reported that hormone therapy failed to improve the quality of life for menopausal women.

60. The "Quality of Life" study which examined the same pool of 16,000 women as the July 9, 2002, WHI study, found that hormone therapy drugs do not do the very thing many women took them for in the first place, that is, to make them feel happier and healthier after menopause. A comparison of women who took hormone therapy to women given a placebo showed those women taking hormones did not report sleeping better or feeling better. The hormone therapy group also did not report feeling less depressed or more sexual satisfaction than the placebo group.

61. According to the study's lead author, Dr. Jennifer Hays: "It's just not something that's going to make most women feel better. Even if it reduces your symptoms, that's not going to translate into a meaningful effect on a quality of life." Dr. Deborah Grady of the University of California, in an accompanying commentary in same issue of the NEJM, said that: "There is no role for hormone therapy in the treatment of women without menopausal symptoms," and that only women who were experiencing debilitating menopausal symptoms should take hormone therapy. She stated further that those women who do continue with hormone therapy should take the lowest possible dose for the shortest possible time.

62. On May 21, 2003, JAMA published another study regarding the efficacy of estrogen plus progestin therapy (e.g., Prempro) for prevention of bone loss in elderly women. The study involved 373 women ages 65 to 90 who had either thinning bones or full-blown osteoporosis and took one of four treatments for three years: (I) combination hormone therapy alone, (ii) a bone-building drug, alendronate (which is sold under the brand name, Fosamax), (iii) combination hormone therapy with Fosamax, or (iv) a placebo.

63. While the study found that the combination of hormone therapy and Fosamax was effective at treatment and prevention of post-menopausal osteoporosis, it also concluded that Fosamax alone was more effective than combination hormone therapy alone. After three years, hip bone density had increased nearly six percent in women on hormone therapy with Fosamax, four percent in those on Fosamax alone, and three percent in the hormones-only group.

64. WHI researcher Dr. Hays, the lead author of the May 8, 2003 JAMA study on hormone therapy and quality of life, said that the findings of the bone-loss study are not convincing enough to recommend hormone therapy for osteoporosis prevention even in older women, especially because the study showed that the bone-enhancing benefits from estrogen come only after long-term use which also carries the highest risk of breast cancer or heart disease.

65. On May 28, 2003, JAMA published yet another study on the effects of hormone therapy, this time focusing on the risk of Alzheimer's disease and other types of dementia. The study found that combination hormone therapy, consisting of both estrogen and progestin, doubled the risk of dementia for woman who started hormones at age 65 or older.

66. The dementia study was based on a four-year experiment involving 4,532 women at 39 medical centers, where half took placebos and half took Prempro. In four years, there were 40 cases of dementia in the Prempro group and 21 in the placebo group. Translated to an annual rate for the population-at-large, the results mean that for every 10,000 women 65 and older taking hormone therapy, there will be 45 cases of dementia a year with 23 of them attributable to hormone use.

67. Dr. Sally A. Shumaker, the director of the dementia study and a professor of public health sciences at Wake Forest University, stated that the study's "clear message is that there's no reason for older women to be taking combination hormone therapy."

68. On June 25, 2003, JAMA published still another study analyzing the data from the Women's Health Initiative, which found that in addition to stimulating the growth of breast cancer, combination hormone therapy makes breast tumors harder to detect, leading to dangerous delays in diagnosis. The report found that breast abnormalities could develop soon after a woman starts taking hormone therapy. Consequently, the study's findings raise questions about the safety of even short-term hormone use. In the same June 25, 2003, issue that reported this study, JAMA also published an editorial by Dr. Peter H. Gann, a cancer epidemiologist at Northwestern University, who stated that this study represents "further compelling evidence against the use of combination estrogen plus progestin hormone therapy."

69. The connection between hormone therapy usage and breast cancer found in the WHI studies were confirmed by a similar study conducted in the United Kingdom. The August 9, 2003, issue of *Lancet* reported on the conclusions reached by *The Million Women Study* – a major research effort funded by Cancer Research UK – confirming that current and recent use of hormone therapy increases a woman's chance of developing breast cancer, and that the risk increases with duration of use. Scientists at the Cancer Research UK analyzed data from over one million women between the ages of 50 and 64. Researchers found that post-menopausal women using combination hormone therapy were twice as likely to develop breast cancer as non-users (a 100% increase).

70. In the August 7, 2003, issue of *NEJM*, the WHI study continued to yield important information regarding the safety of hormone therapy use. The study found that combination hormone therapy does not protect the heart and may even increase the risk of coronary heart disease (CHD). Specifically, the WHI study found that combination hormone therapy usage was associated with a 24% overall increase in the risk of CHD (6 more heart attacks annually per 10,000 women using combination therapy) and a 81% increased risk of CHD in the first year after starting combination therapy.

71. In addition to the studies published in *JAMA, NEJM,* and other medical journals, a recent federal agency report also revealed that estrogen could be dangerous to women taking it as hormone therapy. On December 11, 2002, the National Institute of Environmental Health Sciences released its tenth annual report on carcinogens, which declared for the first time that estrogen is now on the federal government's list of "known human carcinogens."

E. Wyeth Changes Hormone Labels and Reverses Long-Term Marketing Strategy

72. In light of the WHI and NCI studies and other subsequent research reports, the labels provided by Wyeth for its Premarin and Prempro drugs were inadequate, misleading, and inaccurate. In fact, Wyeth changed warning labels on Premarin and Prempro during the last week of August, 2002 to reflect the results of the July, 2002 WHI and NCI studies.

73. Prior to the label change in August, 2002, the Premarin warning label made no mention whatsoever of ovarian cancer.

74. The Prempro label warnings were likewise inadequate prior to August, 2002. As to breast cancer, the Prempro warning explains the risk of breast cancer with conjugated estrogens (the

Premarin component of Prempro), but then adds, with regard to the effect of added progestins on the risk of breast cancer: "The overall incidence of breast cancer does not exceed that expected in the general population." The WHI study plainly reveals that this warning is false and was known or should have been known by Wyeth to be false for decades.

75. The Prempro warnings were also inadequate for two thromboembolic disorders, pulmonary embolisms and blood clots: "The increased risk [of venous thromboembolism] was found only in current ERT [i.e., Premarin only] users." Furthermore, as to cardiovascular disease (heart attacks and strokes), the Prempro warning reads simply, "Embolic cerebrovascular events and myocardial infarctions have been reported," without disclosing the true nature of the risk.

76. Under precautions, the Prempro label acknowledges: "The effects of estrogen replacement therapy on the risk of cardiovascular disease have not been adequately studied." Nevertheless, Wyeth has long promoted the supposed benefits of long term hormone therapy for cardiovascular disease.

77. On January 6, 2003, Wyeth abandoned its long-standing marketing strategy of promoting the long-term use of Premarin and Prempro. Wyeth announced the reversal of its long-held promotional message in a "Dear Doctor" letter to Health Care Professionals that explained it was adopting new labeling for its hormone therapy drugs in light of the WHI findings.

78. According to the January 6, 2003, "Dear Doctor" letter, the labeling changes include boxed warnings:

> [W]hich state that estrogens and estrogens plus progestin therapies should not be used for prevention of cardiovascular disease . . . The boxed warning also includes information [stating that because of the WHI study]

> . . . estrogens and estrogens plus progestin ***should be prescribed for the shortest duration consistent with treatment goals.***

(Emphasis added.)

79. In early June 2003, Wyeth commenced a new public marketing campaign with a full-page advertisement placed in 180 newspapers nationwide. The advertisement, *"A Message from Wyeth,"* disclosed that Wyeth was abandoning its decades-long strategy of promoting long-term usage of Premarin and Prempro for post-menopausal women for a variety of conditions.

> Hormone therapy is not a lifelong commitment. As a result of recent studies, we know that hormone therapy should not be used to prevent heart disease. These studies also report an increased risk of heart attack, stroke, breast cancer, blood clots, and dementia. Therefore, it is recommended that hormone therapy (estrogen, either alone or with progestin) ***should be taken for the shortest duration*** at the lowest effective dose.

(*The Philadelphia Inquirer*, June 1, 2003, at C6; emphasis added).

80. Wyeth had recklessly and willfully failed to conduct adequate pre-approval research and post-approval surveillance to establish the safety of long-term hormone therapy. Nonetheless, Wyeth had promoted long-term hormone therapy use vigorously. The WHI and NCI studies could have and should have been conducted many years ago by Wyeth, before it began its long-term usage marketing campaign. Had it conducted the necessary studies and diligent post-marketing surveillance, Wyeth would have learned years ago that hormone therapy causes cardiovascular diseases, is marginally effective in preventing bone loss, does not promote well-being, causes a number of cancers and dementia, and is even harmful on a short-term basis by increasing the risk of breast cancer.

F. With full knowledge that MPA would be taken by women as the progestin component of their combination hormone therapy, the Defendants made claims regarding the health benefits of MPA that were false and misleading

81. The manufacturers of generic equivalent and brand-name progestin, including the Defendants Pfizer, Pharmacia & Upjohn Company LLC and Greenstone LTD., were aware that their medroxyprogesterone acetate (MPA) would be taken by women as the progestin component of their combination hormone therapy. As a result, the Defendants Pfizer, Pharmacia & Upjohn Company LLC and Greenstone LTD. made claims regarding the cardiovascular and other health benefits of taking their progestin drugs in combination with estrogen that they knew or in the exercise of reasonable care should have known were false and misleading.

82. MPA when used in combination hormone therapy has deleterious effects, including increasing the incidence of strokes, blood clots, heart attacks, breast cancers, and ovarian cancer. In spite of marketing and distributing MPA for use in combination hormone therapy, the Defendants Pfizer, Pharmacia & Upjohn Company LLC and Greenstone LTD. did not warn consumers of the serious adverse side effects of this form of hormone therapy.

83.The Defendants Pfizer, Pharmacia & Upjohn Company LLC and Greenstone LTD. in their manufacture of generic equivalent and brand-name progestin failed to conduct adequate pre-marketing clinical testing and research to determine the safety of MPA when used in combination with estrogen. Furthermore, the Pfizer Defendants in their manufacture of generic equivalent and brand-name progestin failed to conduct adequate post-marketing surveillance to determine the safety of MPA when used in combination with estrogen. Nevertheless, the Pfizer Defendants never disclosed on their warning labels

that such testing had not been performed, thereby fraudulently inducing physicians and patients alike to use the MPA drugs with the false assumption that such drugs had been sufficiently tested.

IV. FRAUDULENT CONCEALMENT

84. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by the Defendants. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on her part. Plaintiffs could not reasonably have discovered the dangerous nature of, and unreasonable adverse side effects associated with, Premarin, Prempro, and medroxyprogesterone acetate prior to July 9, 2002.

85. The Defendants were and are under a continuing duty to disclose to Plaintiffs the true character, quality, and nature of their hormone therapy drugs, including Premarin, Prempro, and medroxyprogesterone acetate. Because of their concealment of the true character, quality and nature of their hormone therapy drugs, Defendants are estopped from relying on any statute of limitations defense.

V. CAUSES OF ACTION

COUNT I – NEGLIGENCE

86. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

87. At all relevant times, Defendants had a duty to exercise reasonable care, and to comply with the existing standard of care, in its preparation, design, research, development, manufacture,

inspection, labeling, marketing, promotion, and sales of its hormone therapy drugs, including Wyeth Defendants' Premarin, the Wyeth Defendants' Prempro and Defendants Pfizer, Pharmacia & Upjohn Company LLC and Greenstone LTD.'s Provera and medroxyprogesterone acetate, which they introduced into the stream of commerce, including a duty to insure their hormone therapy drugs did not cause users to suffer from unreasonable, dangerous or untoward adverse side effects.

88. At all times relevant, Defendants owed a duty to warn consumers of the risks, dangers, and adverse side effects of its hormone therapy drugs properly.

89. Defendants breached their duty of care, and failed to exercise ordinary care in the preparation, design, research, development, manufacturing, inspection, labeling, marketing, promotion, and selling of their hormone therapy drugs, including Premarin, Prempro and Provera - medroxyprogesterone, which it introduced into the stream of commerce, because Defendants knew or should have known that its hormone therapy drugs created the risk of unreasonable, dangerous or untoward adverse side effects.

90. Defendants knew, or in the exercise of reasonable care, should have known that its hormone therapy drugs, including Premarin, Prempro and Provera - medroxyprogesterone were of such a nature that, if not properly prepared, designed, researched, developed, manufactured, inspected, labeled, marketed, promoted, and sold, they were likely to cause injury to those who took their drugs.

91. Defendants breached their duty of care, and failed to use due care, in the manner in which they prepared, designed, researched, developed, manufactured, inspected, labeled, marketed,

promoted, and sold their hormone therapy drugs, including Premarin, Prempro, and Provera - medroxyprogesterone in that they:

(I) Failed to prepare their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(ii) Failed to design their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(iii) Failed to conduct adequate pre-clinical testing and research to determine the safety of their hormone therapy drugs;

(iv) Failed to conduct adequate post-marketing surveillance to determine the safety of their hormone therapy drugs;

(v) Failed to accompany their products with proper warnings regarding all possible adverse side effects associated with the use of their hormone therapy drugs and the comparative severity and duration of such adverse effects;

(vi) Failed to develop their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(vii) Failed to manufacture their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(viii) Failed to inspect their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(ix) Failed to label their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(x) Failed to market their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(xi) Failed to promote their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(xii) Failed to sell their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(xiii) Failed to provide adequate training and information to healthcare providers for the appropriate use of their hormone therapy drugs;

(xiv) Failed to warn Plaintiff and her healthcare providers, prior to actively encouraging and promoting the sale of their hormone therapy drugs, either directly or indirectly, orally or in writing, about the following:

- the need for comprehensive, regular medical monitoring to insure early discovery of potentially fatal strokes, heart attacks, venous thromboembolism, cardiovascular disease, breast cancer, ovarian cancer, and other adverse side effects;
- the possibility of becoming disabled as a result of the use of the drugs;
- the adverse side effects associated with the use of the drugs, including, but not limited to, strokes, heart attacks, venous thromboembolism, cardiovascular disease, breast cancer, and ovarian cancer; and,

(xv) Were otherwise careless and negligent.

92. Despite the fact that Defendants knew or should have known that their hormone therapy drugs caused unreasonable and dangerous side effects, which many users would be unable to remedy by any means, they continued to promote and market their drugs to consumers, including Plaintiff Elizabeth Walsh, when there existed safer and more effective methods of countering the negative health effects of menopause, and of preventing osteoporosis and other disease states claimed by the Defendants to be prevented by its hormone therapy.

93. Defendants knew or should have known that consumers generally, and Plaintiff Elizabeth Walsh specifically, would foreseeably suffer injury as a result of these Defendants' failure to exercise ordinary care.

94. Defendants were or should have been in possession of evidence demonstrating that their products caused serious side effects. Nevertheless, Defendants continued to market their products by providing false and misleading information with regard to their safety and efficacy.

95. As a result of Defendant's conduct, Plaintiff Elizabeth Walsh suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount that will properly, adequately and completely compensate them for the nature, extent and duration of their injuries and damages plus interest, attorneys' fees and costs.

COUNT II –BREACH OF IMPLIED WARRANTY

96. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

97. In the design, manufacture, marketing, distribution and sale of Premarin, Prempro, and Medroxyprogesterone and in the provision of Premarin, Prempro and Medroxyprogesterone to Elizabeth Walsh, Defendants impliedly warranted to the public in general, and to Mrs. Walsh in particular, that the Premarin, Prempro and Medroxyprogesterone designed, manufactured, marketed, distributed, and sold by them, or under their supervision, direction and control, was merchantable and reasonably fit and suitable for the ordinary purposes for which such goods are used, and that the product conformed to the standards imposed by law.

98. The Defendants breached their implied warranties of fitness and merchantability, insofar as Premarin, Prempro and Medroxyprogesterone were placed into the stream of commerce in such a manner as to constitute an unreasonable danger and hazard to Elizabeth Walsh when used for its intended purpose. Contrary to such implied warranty, the Defendants' hormone therapy drugs were not of merchantable quality or safe or fit for their intended use, because the products failed to adequately warn of the dangers associated with their use and as such the products were and are unreasonably dangerous and unfit for the ordinary purposes for which they were sold.

99. Plaintiff Elizabeth Walsh reasonably relied upon the skill and judgment of Defendants as to whether their hormone therapy drugs were of merchantable quality and safe and fit for their intended use.

100. As the direct and proximate cause of the breach of implied warranty, Plaintiff Elizabeth Walsh suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount that will properly, adequately and completely compensate them for the nature, extent and duration of their injuries and damages plus interest, attorneys' fees and costs.

COUNT III – BREACH OF EXPRESS WARRANTY

101. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

102. In the design, manufacture, marketing, distribution and sale of Premarin, Prempro and Medroxyprogesterone, and in the provision of Premarin, Prempro and Medroxyprogesterone to Elizabeth Walsh, Defendants expressly warranted to the public in general, and to Mrs. Walsh in particular, that the Premarin, Prempro and medroxyprogesterone designed, manufactured, marketed, distributed, and sold by them, or under their supervision, direction and control, was merchantable and reasonably fit and suitable for the ordinary purposes for which such goods are used, and that the product conformed to the standards imposed by law, and were safe and efficacious when used as intended.

103. These warranties came in the form of: (i) publicly-made written and verbal assurances of the safety and efficacy of hormone therapy drugs by Defendants, (ii) press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create and increase demand for hormone therapy drugs, which utterly failed to warn of the risks inherent to the ingestion of hormone therapy; (iii) verbal assurances made by Defendants

regarding hormone therapy, and the downplaying of any risk associated with the drugs; (iv) false and misleading written information, supplied by Defendants, and published in the *Physicians' Desk Reference* on an annual basis, upon which physicians were forced to rely in prescribing hormone therapy drugs during the period of Plaintiff's ingestion of hormone therapy drugs, including, but not limited to information relating the recommended duration of the use of the drugs; (v) promotional pamphlets and brochures published and distributed by Defendants and directed to consumers; and (vi) advertisements. The documents referred to in this paragraph were created by and at the direction of Defendants and, therefore, are in their possession and control.

104. The Defendants breached their express warranties of fitness and merchantability, insofar as Premarin, Prempro and medroxyprogesterone were placed into the stream of commerce in such a manner as to constitute an unreasonable danger and hazard to Elizabeth Walsh when used for its intended purpose. Contrary to such express warranties, the Defendants' hormone therapy drugs were not of merchantable quality or safe or fit for their intended use, because the products were and are unreasonably dangerous and unfit for the ordinary purposes for which they were sold. As such, Defendants' products were neither in conformity to the promises, descriptions or affirmations of fact made about these drugs nor adequately contained, packaged, labeled or fit for the ordinary purposes for which such goods are used.

105. Defendant thereafter breached their express warranties to Plaintiff Elizabeth Walsh in violation of the applicable provisions of the state Uniform Commercial Code as amended by: (I) manufacturing, marketing, packaging, labeling, and selling hormone therapy to Plaintiff

Elizabeth Walsh in such a way that misstated the risks of injury, without warning or disclosure thereof by package and label of such risks to Plaintiff Elizabeth Walsh or the prescribing physician or pharmacist, or without so modifying or excluding such express warranties; (ii) manufacturing, marketing, packaging, labeling, and selling hormone therapy to Plaintiff Elizabeth Walsh, which failed to counteract the negative health effects of menopause in a safe and permanent manner and without injury; and (iii) manufacturing, marketing, packaging, labeling, and selling hormone therapy to Plaintiff Elizabeth Walsh, thereby causing her serious physical injury and pain and suffering.

106. Plaintiff Elizabeth Walsh reasonably relied upon the skill and judgment of Defendants as to whether their hormone therapy drugs were of merchantable quality and safe and fit for their intended use.

107. As the direct and proximate cause of the breach of expressed warranty, Plaintiff Elizabeth Walsh suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount that will properly, adequately and completely compensate them for the nature, extent and duration of their injuries and damages plus interest, attorneys' fees and costs.

COUNT IV – FRAUD

108. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

109. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell their hormone therapy drugs, including Premarin, Prempro and

medroxyprogesterone, owed a duty to provide accurate and complete information regarding these products.

110. Defendants' advertising programs, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the impression that the use of their hormone therapy drugs, including Premarin, Prempro and medroxyprogetserone, were safe for human use, had no unacceptable side effects, and would not interfere with daily life.

111. Defendants intentionally encouraged women in general, including Plaintiff Elizabeth Walsh, to remain on hormone therapy for a longer period of time than Defendants knew or should have known was safe and effective.

112. Defendants purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of hormone therapy. Defendants, through promotional literature, deceived potential users and prescribers of the drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying known adverse and serious health effects. Defendants falsely and deceptively kept relevant information from potential hormone therapy users and minimized prescriber concerns regarding the safety and efficacy of its drugs.

113. Plaintiff Elizabeth Walsh justifiably relied to her detriment upon Defendants' intentional misrepresentations concerning their hormone therapy drugs.

114. In particular, in the materials disseminated by Defendants, it falsely and deceptively misrepresented or omitted a number of material facts regarding their hormone replacement

drugs, including Premarin, Prempro and medroxyprogesterone, including, but not limited to, the following:

(I) The presence and adequacy of the testing of its hormone therapy drugs, both pre- and post-marketing; and,

(ii) The severity and frequency of adverse health effects caused by their hormone therapy drugs.

115. Defendants misled both the medical community and the public at large, including Plaintiff Elizabeth Walsh, by making false representations about the safety of their hormone therapy drugs.

116. Defendants were or should have been in possession of evidence demonstrating that their products caused serious side effects. Nevertheless, Defendants continued to market their products by providing false and misleading information with regard to their safety and efficacy.

117. As a result of Defendants' conduct, Plaintiff Elizabeth Walsh suffered these injuries as described with particularity, above.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount that will properly, adequately and completely compensate them for the nature, extent and duration of their injuries and damages plus interest, attorneys' fees and costs.

COUNT V – CORPORATE RESPONSIBILITY: JOINT VENTURES, PARENT/SUBSIDIARIES, AND/OR SUCCESSOR CORPORATION

118. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

119. As a result of their participation in various joint ventures, parent/subsidiary relationships, and/or successor corporations, Defendants are liable to Plaintiffs.

120. As a result of their negligent supervision and actual supervision of various joint ventures, parent/subsidiary relationships, and/or successor corporations, Defendants are liable to Plaintiffs.

121. As a result of the invalidity of various indemnification agreements, Defendants are liable to Plaintiffs.

122. Defendants are liable to Plaintiffs, as alter egos of their joint ventures, parent/subsidiary relationships, and/or successor corporations.

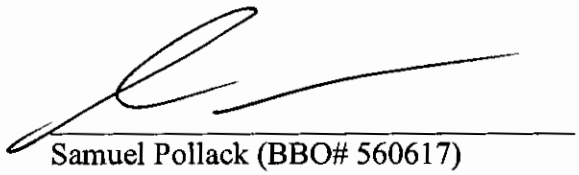
WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount that will properly, adequately and completely compensate them for the nature, extent and duration of their injuries and damages plus interest, attorneys' fees and costs.

DEMAND FOR JURY TRIAL

Plaintiff Elizabeth Walsh hereby demand a jury trial on all claims so triable in this action.

Respectfully submitted,

POLLACK & FLANDERS, LLC



Samuel Pollack (BBO# 560617)
Albert Flanders (BBO# 567076)
50 Congress Street, Suite 430
Boston, MA 02109
(617) 259-3000
(617) 259-3050 (Fax)

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** Elizabeth Walsh v. Wyeth, Inc. et. al.

2. **Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).**

☐	I.	160, 410, 470, 535, R.23, REGARDLESS OF NATURE OF SUIT.	
☐	II.	195, 196, 368, 400, 440, 441-446, 540, 550, 555, 625, 710, 720, 730, 740, 790, 791, 820*, 830*, 840*, 850, 890, 892-894, 895, 950.	*Also complete AO 120 or AO 121 for patent, trademark or copyright cases
☑	III.	110, 120, 130, 140, 151, 190, 210, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 370, 371, 380, 385, 450, 891.	
☐	IV.	220, 422, 423, 430, 460, 480, 490, 510, 530, 610, 620, 630, 640, 650, 660, 690, 810, 861-865, 870, 871, 875, 900.	
☐	V.	150, 152, 153.	

3. **Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.**

4. **Has a prior action between the same parties and based on the same claim ever been filed in this court?**
   YES ☐ **NO** ☑

5. **Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)**
   YES ☐ **NO** ☑
   If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?
   YES ☐ **NO** ☐

6. **Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?**
   YES ☐ **NO** ☐

7. **Do all of the parties in this action, excluding governmental agencies of the united states and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).**
   YES ☐ **NO** ☑

   A. **If yes, in which division do all of the non-governmental parties reside?**
   Eastern Division ☐ **Central Division** ☐ **Western Division** ☐

   B. **If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?**
   Eastern Division ☑ **Central Division** ☐ **Western Division** ☐

8. **If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)**
   YES ☐ **NO** ☑

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Albert C. Flanders, Esq., Pollack & Flanders, LLP
ADDRESS 50 Congress Street, Suite 430, Boston, MA 02109
TELEPHONE NO. 617-259-3000

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Elizabeth Walsh

(b) County of Residence of First Listed Plaintiff Suffolk
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Pollack & Flanders, LLP, 50 Congress St, Suite 430, Boston MA
Tel: 617 259-3000 Fax: 617 259-3050

DEFENDANTS

Wyeth, Inc., Wyeth Pharmaceuticals, Inc. , Pfizer, Inc., Greenstone, LTD, and Pharmacia & Upohn Company

County of Residence of First Listed Defendant Out of State
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

Unknown

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS —Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
Diversity jurisdiction 28 USC 1332

Brief description of cause:
Products liability action concerning hormone replacement drugs

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $ 10,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
07/07/2005

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____